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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,753

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EXAMINER

BADR, HAMID R

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,753	<b>Applicant(s)</b> YOSHIMURA ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/2009, 3/25/2009</u> .                                    | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 7 is objected to for including the name of an institution. The phrase " deposited at International.....FERM BP-6060" should be deleted. Correction is required.

### ***Use Claims***

1. Claim 9 provides for the use of fermented milk whey, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 11 and 14 can be used as claimed and whether claims 11 and 14 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988). Upon applying this test to claims 11 and 14, it is believed that undue experimentation **would** be required because:

(a) *The quantity of experimentation necessary is **great*** since claims 11 and 14 read on "filaggrin synthesis promoting effect" while the specification discloses moisture determination on the cheek of the subject.

(b) There is **no direction or guidance presented** for measurement of filaggrin synthesis in vivo.

(c) There is an **absence of working examples** concerning filaggrin synthesis in vivo.

In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 11 and 14.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 13 is indefinite for “An agent for remedying dry skin for oral intake”. It is not clear what is meant by this phrase. It is suggested to re-write the phrase using any necessary punctuations.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (JP 11-098978 , Machine Translation; hereinafter R1).

8. R1 discloses a fermented milk product produced by lactic acid bacteria and containing large amount of tripeptides such as Val-Pro-Pro and Ile-Pro-Pro. The lactic acid bacteria used are Lactobacillus helveticus CM4 (FERM BP-6060 (page 1, claims 1 and 2 and page 12, paragraph 0055). This is the same strain as presently claimed.

9. R1 discloses that milk of various sources and the skim milk can be used for the fermentation process. (page 6, paragraph 0029).

10. R1 discloses the type of products which can contain the tripeptides as yogurt, beverage, cheese, sour milk, health food, powder, tablets etc. (page 6, paragraph 0032, 0035)

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11. Given that the fermentative activity of *Lactobacillus helveticus* CM4 strain on milk proteins will produce active peptides, the moisturizing effect and filaggrin synthesis promoting effect will be inherent in the fermented products when these products are orally taken in the form of functional foods or purified tripeptides.

12. R1 discloses the measurement of the tripeptide concentration in whey using a high performance liquid chromatography (HPLC) method. (page 9, paragraph 0043).

13. R1 further discloses that the concentration of Val-Pro-Pro in the whey of the sample fermented by the CM4 strain is highest compared to other strains. (page 10, paragraph 0048 and Table 2)

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP H10-045610 (Machine translation, hereinafter R2).

16. R2 discloses fermented milk products such sour milk wherein *Lactobacillus helveticus* has been used as the lactic acid bacteria. (page 1, claims 1-4).

17. R2 discloses the milk raw material sources as regular milk, full fat milk, skim milk, whey, defatted milk. (page 3, paragraph 0009)

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18. R2 discloses other lactic acid bacteria which may be used for that purpose.

Among the lactic acid bacteria disclosed by R2, *Lactobacillus helveticus* ATCC-55796 is the preferred organism. (page 3, paragraph 0012)

19. R2 discloses that food such as yogurt, beverages, cheese, health foods and powders may be used as functional foods of the invention. (page 5, paragraph 0019)

20. R2 does not mention moisturizing and filaggrin synthesis promoting effects of the fermented product as presently claimed, however, since *Lactobacillus helveticus* is a proteolytic organism which produces short peptides in media containing milk, the moisturizing and filaggrin synthesizing effects of the fermented products will be intrinsic when such products are taken orally.

21. Since R2 discloses the raw materials for the fermentation and it also uses the lactic acid bacteria as presently claimed, it would have been obvious to one of ordinary skill in the art to ferment milk and milk products such as whey to produce fermented milk products which could be orally taken as a source of short peptides. The moisturizing and filaggrin synthesizing effects, as presently claimed, would have been intrinsic in these products when taken orally. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in making such fermented products.

### **Conclusion**

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 2000/41572, JP 10-95736, JP 2000-239175. All of these documents disclose fermented milk products using *Lactobacillus helveticus*. They also

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disclose that such fermented products can be used in functional foods, dietary supplements etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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